Rule-Making Cover Sheet

MAPA-1

TO: **Secretary of State**
ATTN: **Administrative Procedure Officer,**
State House Station 101, Augusta, Maine 04333.

2012-60

1. **Agency:** Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. **Agency umbrella and unit number:** 02-392
(2 digit umbrella # and 3 digit unit #)

3. **Title of rule:** Definitions

4. **Chapter number assigned to the rule:** 1
(must be 3 digits or less)

ACCEPTED FOR FILING
MAR - 6 2012
SECRETARY OF STATE

5. **Date(s)/method(s) of notice:** Newspaper advertisement by Secretary of State, 10-12-11; mailing to interested parties, 09-29-11; posting on OPOR's web site, 09-28-11

6. **Date(s)/place(s) of hearing(s):** 11-03-11, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. **Type:** ☐ new rule ☒ partial amendment(s) of existing rule

☐ suspension of existing rule ☐ repeal of rule ☐ emergency rule

☐ repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. **Name/phone of agency contact person:** Geraldine Betts, Board Administrator, (207) 624-8625

9. **If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**

☐ Provisional adoption (prior to Legislative review) ☐ Final adoption

☐ Emergency adoption of major-substantive rule

10. **Certification Statement:** I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on February 2, 2012.

Signature: _____
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. **Approved as to form and legality by the Attorney General on** 3/1/12
(date)

Signature: _____
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Christopher L. Mann

RECEIVED
MAR - 6 2012
OFFICE OF THE SECRETARY OF STATE
AUGUSTA, MAINE

EFFECTIVE DATE:

MAR 11 2012

Part 1-General Information

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 1: DEFINITIONS

Summary: As used in the board's rules, unless the context otherwise indicates, the following words have the following meanings:

[NOTE: Additional definitions are found in 32 M.R.S.A. §13702.]

1-A. APPE. "APPE" is the advanced pharmacy practice experience.

1. **Authorized person**. An "authorized person" is a person other than a pharmacy technician (e.g., computer technician, bookkeeper) who the pharmacist in charge has designated to be present in the prescription filling area in the absence of a pharmacist pursuant to Chapter 13, Section 6(7).

2. **Authorized pharmacy technician**. An "authorized pharmacy technician" is a pharmacy technician authorized by the pharmacist in charge to be present in the prescription filling area during the absence of a pharmacist pursuant to Chapter 13, Section 6(7).

3. **Biological safety cabinet**. "Biological safety cabinet" is a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to NSF International Standard 49, "Class II (Laminar Flow) Biohazard Cabinetry" (February 14, 2003), which the board hereby incorporates into its rules by reference. A copy of Standard 49 is available from-

   NSF International
   P.O. Box 130140
   789 N. Dixboro Road
   Ann Arbor, MI 48113-0140

4. **Blood**. "Blood" is whole blood collected from a single donor and processed either for transfusion or further manufacturing.

5. **Blood component**. "Blood component" is that part of blood separated by physical or mechanical means.

6. **Central fill drug outlet**. "Central fill drug outlet" is a drug outlet that prepares prescription drug orders for dispensing pursuant to a valid prescription transmitted to it by a retail drug

outlet, rural health center or free clinic; or by a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board, and returns the labeled and filled prescriptions to the retail drug outlet or other source of origin for delivery to the patient or the authorized agent of the patient.

7. **Centralized prescription processing**. "Centralized prescription processing" refers to the functions and activities of a central fill drug outlet and a central processing center. A central fill drug outlet and central processing center may, but need not, operate in the same facility.

8. **Central processing center**. "Central processing center" is a drug outlet that performs processing functions including, but not limited to, drug utilization review, claims submission, claims resolution and adjudication, data entry, refill authorizations, interventions and other phone calls for more than one retail drug outlet, rural health center or free clinic; dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not licensed or registered by the board.

8-A. **Certified midwife**. "Certified midwife" means a midwife certified by and in good standing with the North American Registry of Midwives or the American Midwifery Certification Board, provided that "certified midwife" does not include a certified nurse midwife licensed as an advanced practice registered nurse by the State Board of Nursing.

9. **Class 100 environment**. "Class 100 environment" is an atmospheric environment which contains fewer than 100 particles of 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209E, "Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones" (September 11, 1992), which the board hereby incorporates into its rules by reference. A copy of Federal Standard 209E is available from-

Institute of Environmental Sciences
940 E. Northwest Highway
Mount Prospect, IL 60056

10. **Class 1000 environment**. "Class 1000 environment" is an atmospheric environment which contains less than 1000 particles of 0.5 microns in diameter per cubic foot of air according to Federal Standard 209E.

11. **Contact hour**. A "contact hour" is 60 minutes of participation in a continuing professional education activity described in 32 M.R.S.A. §13735 or Chapter 5 of the board's rules.

12. **Cytotoxic**. "Cytotoxic" is a pharmaceutical that is capable of killing living human or animal cells.

13. **DEA**. "DEA" is the United States Department of Justice, Drug Enforcement Administration.

14. **Direct supervision**. "Direct supervision" is the ability of a pharmacist to:

(A) Oversee the actions of a pharmacy technician by being physically present within the same work area as the technician being supervised; ~~or~~

(B) Direct the activities of a pharmacy technician who has no fixed workstation (e.g., visits individual patient rooms); or

(C) Oversee the actions of a pharmacy technician (advanced) at a point of care location remote from the pharmacist in control of an automated pharmacy system. Such supervision shall be exercised via 2-way, real-time voice and video communication between the supervising pharmacist and the pharmacy technician (advanced).

14-A. Drug administration clinic. "Drug administration clinic" is the administration of influenza or other vaccines identified in 32 MRSA §13831 on a mass basis at a scheduled event, with or without sign-up times, within or outside a retail pharmacy, rural health center or free clinic licensed under 32 MRSA §13751. "Drug administration clinic" does not include the administration of influenza or other vaccines to an individual on a walk-in or appointment basis at a retail pharmacy, rural health center or free clinic at any other time.

15. Drug sample. "Drug sample" is a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

16. Electronic device. An "electronic device" includes, but is not limited to, a facsimile machine, computer system, portable device, or any other system or equipment approved by the Board.

17. Electronic signature. "Electronic signature" is an electronic sound, symbol or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

18. Enteral. "Enteral" means within or by way of the intestine.

19. FDA. "FDA" is the United States Department of Health and Human Services, Food and Drug Administration.

20. Hard copy. "Hard copy" is a prescription drug order which has been transferred to paper, whether by hand or by equipment, and is readable without the aid of any special devices.

20-A. IPPE. "IPPE" is the introductory pharmacy practice experience.

21. MPJE(r). "MPJE" is the Multistate Pharmacy Jurisprudence Examination.

22. NABP(r). "NABP" is the National Association of Boards of Pharmacy.

23. NAPLEX(r). "NAPLEX" is the North American Pharmacist Licensure Examination.

24. Nuclear drug outlet. "Nuclear drug outlet" is a drug outlet that compounds, stores, dispenses, labels or delivers any radioactive drug.

25. Parenteral. "Parenteral" is a sterile preparation of drugs for injection through one or more layers of the skin.

26. Pharmacist on duty. "Pharmacist on duty" is a pharmacist who performs the duties of a pharmacist at any given time.

27. Pharmacy intern. "Pharmacy intern" is a pharmacy student or recent graduate engaged in the practice of pharmacy under the direct supervision of a pharmacist while enrolled in the internship program described in Chapter 6 of the board's rules.

27-A. Point of care location. "Point of care location" means the premises where prescriptions filled by an automated pharmacy system that is not wholly located in a retail pharmacy are delivered or administered.

28. Practice setting. "Practice setting" includes, but is not limited to, the place, area, site, or manner in which the practice of pharmacy may normally occur or transpire.

29. Pharmacy technician (advanced). "Pharmacy technician (advanced)" is a pharmacy technician who has demonstrated to the board that he/she:

(1) Holds the designation of Certified Pharmacy Technician (CPhT) issued by the Pharmacy Technician Certification Board, and has maintained the certification in full force and effect; or

(2) Has successfully completed the National Community Pharmacy Technician Training Program and passed the corresponding National Pharmacy Technician examination.

30. Prescription filling area. "Prescription filling area" is the area used for compounding prescription legend drugs, for storing all drugs and devices which may be sold by prescription only, and for any other activities necessary to the practice of pharmacy.

31. Printout. "Printout" is a hard copy produced by computer that is readable without the aid of any special device.

32. Retail drug outlet. "Retail drug outlet" is:

(1) A drug outlet located in a retail store; or

(2) A specialty drug outlet not located in a retail store, including but not limited to a nuclear drug outlet or a drug outlet that compounds sterile pharmaceuticals, that dispenses a drug upon a prescription drug order for a specific patient.

33. Sight-readable. "Sight-readable" refers to a record that may be read from a computer screen, microfiche, microfilm, printout, or other method approved by the Board.

34. Sterile pharmaceutical. "Sterile pharmaceutical" is a dosage form free from living microorganisms (aseptic).

35. Stop date. "Stop date" is the length of time to administer medication. In institutional settings, the physician normally notes the length of time to administer medication on the drug order. In the absence of this notation, the policy of the institution shall determine the length of time various categories of drugs may be administered.

35-A. VAWD. "VAWD" is the Verified-Accredited Wholesale Distributor program administered by NABP.

36. Wholesale distribution. "Wholesale distribution" is the distribution of prescription drugs by wholesale distributors to persons other than consumers or patients, but does not include:

(1) Intracompany sales, which include any internal sales transaction or transfer with any division, subsidiary, parent and affiliated or related company under the common ownership and control as the transferor;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;

(5) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(6) The sale of a drug by a retail drug outlet to licensed practitioners for office use when the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed five (5) percent of that drug outlet's total annual prescription drug sales;

(7) The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

(8) The distribution of drug samples by manufacturers' representatives or distributors' representatives;

(9) The sale, purchase or trade of blood and blood components intended for transfusion; or

(10) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR §203.23.

37. Wholesale distributor. "Wholesale distributor" is anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label

distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. A wholesale distributor includes a wholesaler as defined in 32 M.R.S.A. §~~13702(26)~~13702-A(34).

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13723

EFFECTIVE DATE:
November 8, 2004 - filing 2004-503

AMENDED:
February 9, 2009 – Section 8-A added, filing 2009-48
October 1, 2009 – Section 14-A, filing 2009-510 (EMERGENCY)
November 25, 2009 – Section 14-A, filing 2009-610